Allowed Claims

As amended during interview with Examiner on May 15, 2006 (see claim 1, 18 and 23)

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1. A method for determining an analyte in a sample using an analytical element, the method comprising:

providing a mixture by contacting the sample with a binding partner 2 of a specific binding pair 1 (partner 2 of pair 1), and a binding partner 2 of a specific binding pair 2 (partner 2 of pair 2), wherein partner 2 of pair 1 and partner 2 of pair 2 **are not the analyte and** bind the analyte when the analyte is present in the sample, **wherein the mixture is provided before the mixture is added to the element**;

adding the mixture to a sample application zone of the analytical element, wherein the element comprises a material enabling liquid transport between the sample application zone and a detection zone located downstream thereof, wherein the partner 2 of pair 1 and the partner 2 of pair 2 are not immobilized on the material, wherein the detection zone comprises a binding partner 1 of specific binding pair 1 (partner 1 of pair 1) immobilized in such a manner that it is able to bind to the partner 2 of pair 1, and wherein a labeled partner 1 of specific binding pair 2 (partner 1 of pair 2) is present upstream of the detection zone and impregnated on the material such that it can be detached by liquid and is able to bind to the partner 2 of pair 2 forming, when the analyte is present in the sample, a complex comprising the partner 1 of pair 1, the partner 2 of pair 1, the analyte, the partner 1 of pair 2 and the partner 2 of pair 2, and

detecting the presence or absence of the label in the detection zone, thereby determining the analyte in the sample.

2. The method of claim 1 wherein the specific binding pair 1 and the specific binding pair 2 independently comprise a pair of specific binding partners selected from the group consisting of a hapten and an antibody, an antigen and an antibody, a lectin and a sugar/saccharide, a ligand and a receptor, avidin/streptavidin and biotin, a nucleic acid and a nucleic acid.

3. The method of claim 1 wherein the partner 1 of pair 2 is an antibody against the partner 2 of pair 2.

4. The method of claim 3 wherein the partner 1 of pair 2 is an antibody against digoxigenin or digoxin.

5. The method of claim 1 wherein the partner 1 of pair 2 is labeled with an enzyme or direct label.

6. The method of claim 5 wherein metal or latex particles are used as the direct label.

7. The method of claim 1 wherein the partner 1 of pair 2 is located in the sample application zone.

8. The method of claim 5 wherein the partner 1 of pair 2 is located in the sample application zone.

9. The method of claim 1 wherein an antibody for specific binding with an antigen or hapten is conjugated with the partner 2 of pair 1 and the antibody is conjugated with the partner 2 of pair 2.

10. The method of claim 1 wherein an antigen, hapten or oligopeptide is conjugated with the partner 2 of pair 1 and the antigen, hapten or oligopeptide is conjugated with the partner 2 of pair 2, wherein the antigen, hapten or oligopeptide specifically binds to an antibody.

11. The method of claim 1 wherein the partner 2 of pair 1 and the partner 2 of pair 2 are in separate containers prior to providing the mixture, wherein the separate containers do not include